

# **Quality Management Plan**

**for**

## **EPA Region 4**

**U.S. Environmental Protection Agency**

**Region 4**

**61 Forsyth Street, SW  
Atlanta, Georgia 30303**

**Revision 2**

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## **LIST OF ACRONYMS**

**APTMD** - Air, Pesticides and Toxics Management Division  
**ARCS** - Alternative Remedial Contracting Strategy  
**ASB** - Analytical Support Branch  
**CERCLA** - Comprehensive Environmental Response, Compensation and Liability Act  
**CFR** - Code of Federal Regulations  
**CLP** - Contract Laboratory Program  
**CID** - Criminal Investigation Division  
**CO** - Contracting Officer  
**COE** - U.S. Army Corps of Engineers  
**CSI** - Compliance Sampling Inspection  
**CWA** - Clean Water Act  
**DMRQA** - Discharge Monitoring Report Quality Assurance  
**DQO** - Data Quality Objectives  
**EAB** - Ecological Assessment Branch  
**EIB** - Environmental Investigations Branch  
**ESAT** - Environmental Services Assistance Team  
**FAR** - Federal Acquisition Regulations  
**FIFRA** - Federal Insecticide, Fungicide and Rodenticide Act  
**FOIA** - Freedom of Information Act  
**GIS** - Geographic Information System  
**GMO** - Grants Management Office  
**IAG** - Interagency Agreement  
**IM** - Information Management  
**NDPD** - National Data Processing Division  
**NEPA** - National Environmental Policy Act  
**NERL** - National Environmental/Exposure Research Laboratory  
**NPL** - National Priority List  
**NPDES** - National Pollutant Discharge Elimination System  
**NTSD** - National Technology Services Division  
**OEI** - Office of Environmental Information

**OPM** - Office of Policy and Management (Region 4)  
**OQADI** - Office of Quality Assurance and Data Integration  
**PAI** - Performance Audit Inspection  
**PE** - Performance Evaluation  
**PO** - Project Officer  
**QA** - Quality Assurance  
**QMP** - Quality Management Plan  
**QAPP** - Quality Assurance Project Plan  
**QAWG** - Quality Assurance Workgroup  
**QC** - Quality Control  
**RCRA** - Resource Conservation and Recovery Act  
**RQAM** - Regional Quality Assurance Manager  
**RA** - Regional Administrator  
**SDWA** - Safe Drinking Water Act  
**SESD** - Science and Ecosystem Support Division  
**SOP** - Standard Operating Procedure  
**START** - Superfund Technical Assistance and Response Team  
**TSCA** - Toxic Substances Control Act  
**TEP** - Technical Evaluation Panel  
**TVA** - Tennessee Valley Authority  
**USGS** - United States Geological Survey  
**UST** - Underground Storage Tank

## 1.0 QUALITY MANAGEMENT PLAN IDENTIFICATION FORM

Document Title Quality Management Plan  
Organization Title EPA Region 4  
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**Plan Coverage:** This management plan documents the quality system used in EPA Region 4 and is required by EPA Order 5360.1 A2, "Policy and Program Requirements for the Mandatory Agency-Wide Quality System." The plan covers quality assurance policies, roles and responsibilities for environmental data collection activities. This includes the collection, evaluation, and use of environmental data produced by regional programs and data generated through grants, contracts, interagency and cooperative agreements. In addition, the plan covers environmental technology which is funded by the Agency whose purpose is to prevent pollutants from entering the environment or to remove pollutants from the environment.

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## **2.0     INTRODUCTION**

EPA Order 5360.1 A2, Policy and Program Requirements For the Mandatory Agency-wide Quality System, requires that each EPA Program and Regional Office develop and document a quality system to assure that environmental data used to support Agency decisions is of adequate quality and are usable for their intended purpose. This Quality Management Plan (QMP) describes Region 4's quality system. A quality system is a structured and documented management system which describes an organization's roles, responsibilities, policies, and procedures as they relate to the generation and use of environmental data and the implementation of environmental technology. This document is intended for use by EPA Region 4 managers and staff, as well as those organizations producing environmental data under an EPA extramural agreement, i.e., contract, grant, cooperative agreement, and interagency agreement. The document provides a link between quality assurance (QA) policy as defined in EPA Order 5360.1 A2, and the implementation of this Agency Directive in Region 4. It is important to note that this plan does not cover all Region 4 management systems, but only those which are related to the generation and use of environmental data and the use of environmental technology.

### **2.1     Importance of Environmental Data**

Environmental data are a critical input to the Agency's decisions to protect human health and the environment. Most of the decisions which are made in the region concerning the management of the environment and the reduction of risk ultimately require the use of environmental data which are generated by EPA, or by state, tribal, local government, and/or private sector organizations. Therefore it is critically important that decision makers know the origin and quality of the environmental data used in these decisions. The quality of environmental data are known when all components associated their derivation (precision, bias, completeness, comparability, sensitivity, and representativeness) are documented.

### **2.2     Essential Definitions**

The following definitions are essential to understanding the roles, responsibilities, policies, and procedures outlined in this document.

2.2.1    Quality System - A structured and documented management system describing the quality assurance policies and procedures for (1) ensuring that environmental data are of known and documented quality; and, (2) that environmental technology is designed, constructed and operated in a manner to produce the desired environmental results.

2.2.2    Environmental Data - Information collected directly from measurements, produced



from models, or compiled from other sources such as data bases or literature, which are used for decision making purposes.

2.2.2.1 Internal Data - Data generated by or for Region 4 programs where regional staff have primary responsibility for project or task decision making. Region 4's quality assurance system requirements apply to these data. Regional contracts which produce environmental data for regional programs (air , water or waste) also fall into this category.

2.2.2.2 Extramural Data - Data generated by organizations other than Region 4 which are funded by EPA through grants, cooperative agreements, contracts and/or interagency agreements. Overall EPA quality assurance requirements for financial assistance agreements, covered in 40 CFR 30.54 and 31.45, apply to these data.

- 2.2.3 Environmental Technology - Pollution control devices and systems, waste treatment processes and storage facilities, and site remediation technologies which are used to remove contaminants from the environment or prevent contaminants from entering the environment.
- 2.2.4 Quality Assurance (QA) - An integrated system of activities including planning, implementation and assessment to ensure that environmental data are of known and documented quality, and that environmental technology produces the desired results.
- 2.2.5 Quality Control (QC) - The overall system of technical activities that measure the performance of a process or item against defined standards to ensure that the process or item meets the pre-defined standards of the customer.
- 2.2.6 Quality Assurance Project Plan (QAPP) - A critical planning document for a project or task, describing how data collection activities are planned, implemented and assessed.
- 2.2.7 Data Quality Objectives (DQOs) - A systematic planning system designed to produce qualitative and quantitative statements that clarify project objectives, define the appropriate type of environmental data, and specify tolerable levels of decision error.
- 2.2.8 Graded Approach - The process of selecting the elements needed in a project-level planning document based on the degree of confidence needed in the environmental

data and the intended use of the results.

### **3.0 REGIONAL QUALITY ASSURANCE POLICY and GOALS**

#### **3.1 Regional QA Policy**

Region 4 is strongly committed to sound science and quality assurance (QA) practices which will produce environmental data of appropriate quality to be used for decision making. This commitment is consistent with the goals of EPA Order 5360.1 A2. It is the policy of Region 4 that all decisions which are made to safeguard the environment and protect human health will include a consideration of the quality of environmental data and/or environmental technology which supports the decision. Regional policy also includes a commitment by management that the quality system supporting the generation of data of known quality and effective environmental technology will be implemented as described in this plan. The Region 4 policy is achieved by ensuring that adequate and acceptable planning, implementation, and assessment procedures are utilized through all phases of projects/tasks which require the generation of environmental data and/or the use of environmental technology.

Regional managers and staff will assure that there are sufficient QA activities conducted by the environmental programs to provide reasonable confidence that all environmental data generated are scientifically valid, of adequate statistical quantity, of known precision and bias, of acceptable completeness, representativeness, and comparability, and where appropriate, legally defensible. Environmental data quality is the responsibility of all EPA Region 4 staff who are directly or indirectly involved in the generation of data. Senior managers in each division are responsible for assuring that adequate resources, including personnel, travel funds, and extramural funds, are available to implement the regional quality assurance system.

#### **3.2 Regional QA Objectives**

The following are the regional objectives which serve to support the regional policy:

- 3.2.1 Regional QA System activities shall comply with ANSI/ASQC E-4, “Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs”, 1994, with respect to planning, implementing and assessing quality assurance activities. In addition, all environmental technology constructed for pollution prevention, control, or waste remediation are designed, constructed and operated according to pre-defined specifications. Specific quality assurance implementation policy for environmental

technology will be developed as guidance is provided by the Office of Environmental Information, Quality Staff.

- 3.2.2 The data quality objectives (DQO) process, or a similar systematic planning process, shall be used to plan project goals and objectives as they relate to needed environmental data quality prior to the initiation of data collection activities. DQOs, or similar outputs from a systematic planning process, shall be documented in a quality assurance project plan, or equivalent project-level planning document.
- 3.2.3 QA Project Plans (QAPPs), or equivalent planning documents, however named, shall be developed by those staff (either EPA or contractor) responsible for designing and implementing a project, study, or task which requires the collection or use of environmental data. QAPPs or other equivalent planning documents shall be approved by the appropriate designated regional official prior to project implementation. QAPPs and equivalent planning documents shall meet EPA requirements and will incorporate project-specific DQOs.
- 3.2.4 Extramural organizations which receive EPA extramural funding shall document their quality systems in EPA-approved Quality Management Plans.
- 3.2.5 Regional managers and staff shall receive QA training appropriate for their responsibilities related to data collection or environmental technology.
- 3.2.6 Communication on QA issues and activities shall be maintained among the Regional Quality Assurance Manager, program managers and staff.
- 3.2.7 Assessments shall be performed to determine the effectiveness of Regional and extramural quality systems.
- 3.2.8 QA processes shall be designed in the most cost-effective manner without compromising data quality. Continuous improvement in the quality management system shall be emphasized.

#### **4.0 REGIONAL ORGANIZATION and QA RESPONSIBILITIES**

##### **4.1 Regional Program Organization and Function**

Region 4's organizational structure is shown in Appendix A. Major program elements and activities are shown in Appendix B. The role of each regional program organizational unit covered by the QA requirements is briefly described below:

#### 4.1.1 Science and Ecosystem Support Division (SESD)

The Division has overall management responsibility for the regional quality system. The regional quality assurance manager is organizationally located within the immediate office of the Division Director. This Division also is the primary organization within Region 4 responsible for the collection of environmental data. The Division conducts field investigations, inspections, projects, and studies which often require sampling of environmental media. SESD also analyzes multi-media environmental samples; processes and evaluates multi-media environmental data; and prepares project or study reports which summarize results and/or provide conclusions and recommendations. All investigations and projects are done at the request of the regional program divisions based on memoranda of agreement and work plans negotiated annually between SESD and the program divisions. SESD performs specific QA assessments of selected external environmental monitoring projects as requested by the program divisions.

#### 4.1.2 Air, Pesticides & Toxics Management Division (APTMD)

The Division has the program management and implementation responsibilities for the Clean Air Act (CAA), Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA). It serves as the technical/program authority for all monitoring activities associated with the CAA, FIFRA, and TSCA. It ensures that QA matters are reflected in budgets, program plans, and work/operating plans. The division manages grants, contract funds, and cooperative agreements, and overviews external environmental monitoring programs which require the collection of environmental data. SESD provides the APTMD with technical assistance relevant to monitoring and data processing activities, including QA oversight.

#### 4.1.3 Waste Management Division

The Division has the program management and implementation responsibilities for the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), Resource Conservation and Recovery Act (RCRA), and Emergency Response Programs. It manages federal grants and contract funds. The Division ensures that QA matters are properly reflected in budgets, program plans, and work/operating plans. It serves as technical/program authority for all hazardous waste environmental monitoring activities within the geographical boundaries of Region 4. The data arising from these programs are the product of efforts both internal and external to the Region. The division overviews external environmental monitoring programs which require the collection of environmental

data. SESD provides the Waste Management Division with technical assistance relevant to the collection of environmental data, including QA oversight. This includes regional management of the Contract Laboratory Program (CLP), review of CLP and regional contract lab data, systems audits of state field and laboratory activities, and overview of potentially responsible parties' remedial actions at CERCLA sites.

#### 4.1.4 Water Management Division (WMD)

This Division has the program and implementation responsibilities for the Safe Drinking Water Act (SDWA), Clean Water Act (CWA), ambient surface water and groundwater, underground injection control, estuarine waters, off-shore discharge, and domestic and industrial wastewater treatment programs. It is responsible for oversight of delegated permitting and compliance as well as the delegated enforcement for municipal and industrial wastewater treatment facilities. The division manages federal grants and contract funds. It ensures that QA matters are properly reflected in budgets, program plans, work/operating plans. WMD serves as the technical/program authority for all water-related environmental monitoring activities within the geographical boundaries of Region 4. The data arising from these programs are the product of efforts both internal and external to the Region. The division overviews external environmental monitoring programs which require the collection of environmental data. SESD provides the WMD with technical assistance relevant to monitoring and data collection and interpretation activities, including QA oversight. This includes oversight of State/Tribal/Local fixed, ambient water monitoring networks, special ambient water studies, performance audits on water and wastewater field monitoring and laboratory operations, NPDES compliance inspections and oversight inspections (CSI's and PAI's) and systems audits of state field and laboratory activities.

#### 4.1.5 Environmental Accountability Division (EAD)

This Division has the overall planning and accountability responsibility for enforcing the various environmental statutes which the Region implements. These responsibilities include: (1) integrating compliance assurance activities to facilitate multi-media projects at the Regional and State/Tribal/Local levels; (2) performing the planning and targeting necessary for the Region's compliance assurance plan, (3) assisting the media programs in developing strategies and tools for assisting the regulated community in achieving compliance with Agency statutes; (4) assessing the environmental plans developed by other Federal agencies as required by the National Environmental Policy Act (NEPA) and Section 309 of the Clean Air Act; (5) supporting the environmental compliance activities carried out by Tribal

governments; (6) providing legal support for enforcement actions relative to violations of Agency statutes and regulations; and (7) providing legal counsel to the Region's senior management and operating programs.

The legal and technical programs within EAD do not normally require monitoring or measurement activities which involve data collection. In limited instances, it may be necessary for EAD to arrange for environmental measurements in order to properly assess the environmental plans submitted by other Federal agencies under NEPA. In these instances, field and laboratory data are collected by EPA contractors in accordance with delivery orders and a QAPP. SESD provides EAD with technical assistance upon request by reviewing environmental impact statements and may conduct special studies as requested involving sampling and analyses.

#### 4.1.6 Office of Policy and Management (OPM)

This office has the responsibility for human resources management, budget and finance, procurement and grants administration, information management, and planning and analysis.

Within OPM's Grants and Procurement Branch, the Grants Management Office (GMO) is responsible for the business management aspects associated with financial assistance agreements (grants and cooperative agreements). This includes the review and negotiation of applications, and the award and administration of funded projects (from project initiation through final close-out). GMO is also tasked with the administrative management responsibility of coordinating and controlling the Interagency Agreement (IAG) process within the Region. GMO reviews the regional programs' decision memoranda for both assistance agreements and IAGs to confirm that QA has been addressed in accordance with 40 CFR 30.54 and 31.45 whenever the agreements involve environmental measurements or technology. If the scope of work involves environmental measurements or technology, and a QA Management and/or QAPP has not been approved by the RQAM, the grant or IAG is conditioned to require the appropriate plan before any environmental measurements or data collection may begin.

Within the Grants and Procurement Branch, the Procurement Section has the responsibility for contracting for goods and services. The QA requirements in the Federal Acquisition Regulations (FAR) 46.202-4 and FAR 52.246-11 (*Higher-Level Contract Quality Requirement*, Feb 1999) apply to regional procurements involving environmental data. EPA has selected ANSI/ASQC E-4, "Specifications and Guidelines for Quality Systems for Environmental Data Collection and

Environmental Technology Programs,”1994, as the quality standard which contractors must meet. Implementation of this standard for contracts is further defined in EPA Order 5360.1 A2, as well as EPA Directive 1900, the Agency’s Contract Management Manual.

OPM’s Information Management Branch is responsible for developing and implementing policies and guidance to ensure information management (IM) resources are efficiently, economically and effectively utilized throughout the Region. The Branch reviews and approves requests for IM acquisitions and services to ensure conformity with policy directives and specifications. This organization also provides management and operational support for the integration of environmental data into Geographic Information Systems (GIS). GIS are software and hardware systems used by media programs and support organizations to more efficiently and accurately analyze and interpret environmental data. While the Information Management Branch does not generate environmental data, it is responsible in cooperation with the appropriate media program, for assuring that the data used in GIS, computer models and databases are suitable for their intended use.

SESD provides OPM with technical assistance by reviewing QAPPs, Quality Management Plans, and contract Scopes of Work.

#### 4.1.7 Gulf of Mexico Program Office

The Gulf of Mexico Program Office (GMPO) was initiated by the U.S. Environmental Protection Agency (EPA) in 1988 as a non-regulatory program. Organizationally, the program falls within the Region 4 management structure. The program was developed because no single agency or level of government had either the necessary technical or financial resources, or the legal mandate to address the spectrum of environmental and public health issues facing the Gulf. The Gulf Program is today a collaborative effort that includes a consortium of key stakeholders that share significant interests in coastal and marine resources . It is an ecosystem-based approach founded on the principles of bringing the appropriate science, together with the financial and technical resources, to help the Gulf States and coastal communities effectively address their environmental problems within a broader regional and national context.

Normally GMPO staff do not directly perform environmental data collection. Staff are involved in managing grants and interagency agreements, providing technical/scientific support to stakeholders within the Gulf region, and coordinating scientific studies in order to achieve common goals.

SESD provides GMPO with technical assistance by reviewing QAPPs, Quality Management Plans, and contract Scopes of Work.

Appendix B further identifies Regional program roles and responsibilities by listing major mission elements (data gathering activities), the responsible Division/Branch, and the SEDS Organizations that provide support. It also indicates those programs that have been delegated to the states.

## 4.2 Quality Assurance Responsibilities

Regional managers and staff have the following responsibilities for the quality system.

### 4.2.1 Regional Administrator (RA)

The RA has the overall responsibility for the development, implementation, and continued operation of the Regional QA Program. The responsibility for managing the day-to-day QA activities within the Region are assigned to the Regional Quality Assurance Manager.

### 4.2.2 Regional Quality Assurance Manager (RQAM)

The RQAM, located within SEDS, has the authority and responsibility for managing the QA activities within the Region. The RQAM is independent of any data generation activities within SEDS or the Region. The RQAM may require suspension of environmental data collection projects and request corrective action in the event that data quality/environmental technology QA activities do not meet Agency QA policy or requirements. In the event that the RQAM determines that any regional data collection activities (at the project or program level) do not meet Agency quality assurance policies or requirements, the RQAM shall have the prerogative to meet with the Regional Administrator or Deputy Regional Administrator (RA/DRA) if discussions with the appropriate divisional senior management fail to resolve the issue(s). A meeting between the RQAM and Regional Administrator (or Deputy Regional Administrator) to discuss QA issues will be preceded by written notification from the RQAM to the SEDS Director/Deputy and RA/DRA.

The RQAM is organizationally located in the Office of Quality Assurance and Data Integration (OQADI), SEDS. The RQAM currently serves as the Chief (first level supervisor) of this Office and reports directly to the Director/Deputy Director of SEDS. OQADI staff perform the following functions:

- ▶ Verify and validate environmental data produced by laboratories under



- contract to the Region.
- ▶ Review QMPs and QAPPs and recommend approval status of these plans to the RQAM.
  - ▶ Perform laboratory assessments of state, commercial, tribal, and/or other government laboratories as required by SDWA, CWA, and CLP.
  - ▶ Perform assessments, including management system assessments, data quality audits, and performance audits.
  - ▶ Manage and administer the regional Environmental Services Assistance Team (ESAT) Contract. **Note: While some areas of the ESAT contract involve data generation, OQADI personnel do not serve as work assignment managers for these task areas and do not have responsibility for data generated by the ESAT contractors.**
  - ▶ Perform graphical and locational evaluation of data using geographic information systems and software.

Staff from the SESD Superfund and Air Section perform QA assessment activities, including technical system assessments, data quality audits, and performance audits required by the Clean Air Act.

Additionally, the RQAM:

- 4.2.2.1 Serves as the official Regional contact for all QA matters in the Region by providing advice, guidance, assistance and training as needed or requested by regional managers and staff.
- 4.2.2.2 Advises staff on development of QAPPs for internal data. This may include explanation of and/or review of the data quality objective process. The RQAM will not review a QAPP which he/she has participated in developing, but will delegate the review to another staff member.
- 4.2.2.3 Reviews, comments, and approves QAPPs for internal and external Regional data operations (see section 2.1.2), except where State/Tribal agencies have been granted QAPP approval authority. Reviews implementation of selected QA plans and adequacy of the data generated from a quality perspective.
- 4.2.2.4 Serves on the Regional Peer Review Panel which has been established (Regional Order 2200.1) to review and approve study plans and reports for major special studies, and other technical documents for publication and distribution. This review process helps ensure that Agency QA requirements are incorporated in all

major monitoring activities.

- 4.2.2.5 Assists Regional programs in integrating EPA QA Program requirements into the State/Tribal grants and into contract/IAG scopes of work.
- 4.2.2.6 Assists State/Tribes and other grantees in the development and implementation of QA Management and Project Plans.
- 4.2.2.7 Coordinates and/or conducts system and performance audits of selected environmental monitoring programs.
- 4.2.2.8 Submits annual QA Status Report and Work Plan to Regional management and EPA's Quality Staff Director.
- 4.2.2.9 Coordinates and participates in the OEI Quality Staff review of the Region 4 quality system.

#### 4.2.3 Regional Managers

Division/Office Directors are responsible for ensuring that internal and extramural data collection activities within their programs are conducted in accordance with Agency and Region 4 QA policy. Daily QA management is the responsibility of the appropriate second or first level managers (i.e., Branch and Section Chiefs). The line managers are responsible for procedures within their area of responsibility to ensure the acceptability of data and the suitability of environmental technology. Key responsibilities of managers are:

- 4.2.3.1 Establish planning policies to ensure that appropriate QA procedures are reflected in budgets, program plans, and operating plans.
- 4.2.3.2 Encourage the development of Data Quality Objectives (DQO's) for data collection activities.
- 4.2.3.3 Require the development of QAPPs or an equivalent project-level planning document for projects involving data collection.
- 4.2.3.4 Support regional quality system implementation and assessment.

4.2.3.5 Take corrective action as required by QA assessments or reviews.

4.2.3.6 Report data quality problems to RQAM.

4.2.3.7 Assure staff receive appropriate QA training.

#### 4.2.4 Quality Assurance Workgroup (QAWG)

QAWG members serve as the QA contact persons for their Division, Office and/ or program. The function of the QA Workgroup is to serve a conduit for communication on quality issues within the region. Each Division/Office director will appoint at least one manager or staff person to the QAWG. Key responsibilities of the QAWG members are:

4.2.4.1 Serve as the official Division/Office contact for quality assurance matters pertinent to the data collection activities of that Division/Office/Program.

4.2.4.2 Attend called meetings of the QAWG to keep abreast of QA issues affecting the Region and Agency. Communicate QA issues to Division/Office personnel.

4.2.4.3 Advise the RQAM on changes needed to the Regional Quality Management Plan. Coordinate program input for the Regional QA Annual Report submitted by the RQAM to Quality Staff Director.

4.2.4.4 Respond to quality control issues and problems, and respond to requests for guidance or technical direction.

4.2.4.5 Work with the Division's staff to develop and maintain an effective QA program.

4.2.4.6 Attend Regional QA training provided by the RQAM or QAD in the Region as appropriate.

#### 4.2.5 Regional Project Managers

Project Managers are responsible for specific internal (see section 6.1) regional projects. Therefore, the Project Manager has the principal responsibility for ensuring that project objectives are met and that the data collected to support project decisions meet national and regional QA requirements. Key responsibilities

of the Project Manager are:

- 4.2.5.1 Prepare or direct the preparation of a QAPP (or equivalent planning document) for each project and submit the QAPP to the RQAM for review/approval.
- 4.2.5.2 Prepare or approve Data Quality Objectives, specifications, and acceptance criteria for environmental data needed to support project decisions..
- 4.2.5.3 Participate in conducting QA system/performance audits of projects as requested by the RQAM.
- 4.2.5.4 Take corrective action that may be required by audit findings.
- 4.2.5.5 Report data quality problems to regional QA Workgroup representative.
- 4.2.5.6 Attend appropriate regional QA training provided in the region.

#### 4.2.6 Regional Project Officers

Project Officers are accountable for specific extramural assistance agreements (see section 5.2) or contracts. Therefore, while the Project Officers are normally not directly involved in project activities, the Project Officer has the overall responsibility for ensuring that all Agency QA requirements are met by the assistance agreement recipient or contractor. Key responsibilities of the Project Officer are:

- 4.2.6.1 Require preparation of a Quality Management Plan and/or a QA Project Plan, as appropriate, for each assistance agreement or contract.
- 4.2.6.2 Overview data quality generated from external projects funded through financial assistance agreements and/or contracts.
- 4.2.6.3 Participate in conducting QA system and performance audits of projects as requested by the RQAM.
- 4.2.6.4 Coordinate review of external QMP and/or QAPPs and submit to RQAM for review and approval. In situations where the project is

funded through a State/Tribal continuing environmental program grant, that organization may be delegated the responsibility for QAPP review/approval (see Section 5.1.2).

- 4.2.6.7 Take corrective action that may be required by audit findings.
- 4.2.6.8 Report data quality problems to regional QA Workgroup representative.
- 4.2.6.9 Attend appropriate regional QA training.

#### 4.2.7 Regional Program Technical Staff

Technical staff will support the RQAM by providing technical assistance in their area of expertise if requested by the RQAM. This will enhance the QA capability in Region 4. The specific duties which will be assigned to the technical specialists are as follows:

- 4.2.7.1 Assist RQAM with technical aspects of QA as related to their expertise in air, water, toxic substances, hazardous waste, engineering, chemistry, biology, microbiology, field operations and data operations.
- 4.2.7.2 Identify QA needs, resolve problems, and answer requests for guidance or assistance in area of expertise.
- 4.2.7.3 Conduct and/or participate in on-site field and laboratory system and technical audits.
- 4.2.7.4 Participate in technical assistance and training of State/Tribal/local, and private laboratory personnel in EPA methods, instrumental and QA requirements.

#### 4.2.8 Designated Approving Officials

A designated approving official (DAO) is a regional manager or staff person who has been delegated the authority to approve quality assurance project plans by the RQAM. The DAO will follow prescribed procedures for reviewing, documenting, and approving QAPPs. The DAO must meet minimum training requirements. See Section 6.2 for additional details.

## **5.0 REGIONAL QUALITY SYSTEM REQUIREMENTS for EXTERNAL ORGANIZATIONS**

Within the Region, QA data generation activities fall into two broad categories:

- a. External: data generated by organizations receiving grants, cooperative agreements, and interagency agreements; and,
- b. Internal: data generation projects designed and conducted by Regional EPA staff and/or EPA contractors.

### **5.1 State, Local, and Tribal Grants**

A substantial amount of environmental data required by EPA statutes and regulations are generated by state, local, and tribal organizations receiving one-time or continuing environmental grants. To qualify for financial assistance, state, local, and tribal organizations must meet the QA specifications of 40 CFR Part 31.45, which require that the “grantee shall develop and implement quality assurance practices consisting of policies, procedures, specifications, standards and documentation sufficient to produce data of quality adequate to meet project objectives...”.

5.1.1 In order to satisfy the QA requirements in 40 CFR Part 31.45, the assistance agreement recipient must submit a Quality Management Plan for review and approval by the Region 4 QA Manager and the appropriate assistance agreement Project Officer (PO). Approval of the QMP is a joint responsibility of the RQAM and PO and requires approval by both parties. In order for a grantee’s QMP to be approved, the grantee’s quality system must meet the specifications of EPA Requirements for Quality Management Plans (EPA QA/R-2), March 2001 (or most recent edition). If grantees make sub-awards (either sub-grants or procurement) under an assistance agreement, they must ensure that the sub-awards meet the quality assurance requirements in EPA QA/R-2.

5.1.2 Clarifying language provided by EPA’s Office of Grants and Debarment also requires the grant recipient to provide a QAPP in addition to the QMP. This requirement is feasible if the grant applies to only one or two projects. However, in the instance where the grant is a continuing grant or performance partnership grant (PPG), there are usually a number of individual data collection activities or projects which require a QAPP to document specific project activities covered by the grant. Due to resource and time constraints, it is not feasible for the RQAM to review individual QAPPs for a large number of projects covered by a continuing grant or PPG.

If a State/Tribal agency is operating under a QMP approved by Region 4, the

Region 4 program division responsible for administering the grant may delegate the responsibility for reviewing and approving QAPPs to the grantee, after obtaining concurrence from the RQAM. In order for the delegation to occur, the State/Tribal QMP must include procedures for the development, review, and approval of Quality Assurance Project Plans for specific data collection projects. Within the regional program administering the grant, the delegation for QAPP approval to the State/Tribal organization must occur at the second level management authority (Branch Chief) or higher and be made after consultation with the RQAM. The Region 4 program responsible for administering the grant must assure that the procedures described in the State/Tribal QMP for the development, review, and approval of Quality Assurance Project Plans have actually been implemented by the State/Tribal Agency.

- 5.1.3 While state, tribal and local agencies are responsible for managing the QA programs under their grants, the Region retains overview responsibilities. The major overview functions are work plan reviews and program evaluations. QA input for these overview functions include Quality Management Plan review/approval and on-site QA audits of field and laboratory operations. State program overview is the primary responsibility of the individual regional program division/office with assistance from the RQAM and SESD personnel as requested.

## 5.2 Academic, Hospital, and Non-Profit Grants and Cooperative Agreements

40 CFR Part 30.54, contains QA requirements for grants and cooperative agreements with institutions of higher education, hospitals and other non-profit organizations. Section 30.54 states: "If the Project Officer determines that the grantee's project involves environmentally related measurements or data generation, the grantee shall develop and implement quality assurance practices consisting of policies, procedures, specifications, standards and documentation sufficient to produce data of quality adequate to meet project objectives...". These grants are usually one-time assistance agreements as opposed to the continuing grants awarded to state, local and tribal organizations. The academic/non-profit QA requirement is satisfied by the grantee's submission of a QMP and QAPP, with subsequent approval of the QMP and QAPP.

The QMP and QAPP may be combined into a single document if the RQAM and Project Officer agree that the nature and extent of the environmental data collection effort warrants such action. QMPs and QAPPs will be approved by the Region 4 QA Manager and the appropriate Project Officer(s). QMPs must be approved prior to award of the financial assistance. It is recommended that QAPPs be approved prior to award, however if the QAPP is not approved prior to award, then the assistance agreement will be conditioned to require an approved QAPP before data collection begins. If grantees make

sub-awards (either sub-grants or procurement) under an assistance agreement, they must ensure that the sub-awards meet the quality assurance requirements of

### 5.3 QA Operations for Interagency Agreements

For interagency agreements, before funding for environmental measurements or data collection activities is approved, EPA Region 4 and the other involved organizations must have agreed upon the QA requirements for the project. The RQAM shall review and approve QA Management/Project Plans, as appropriate, prior to award of the inter-agency agreement. The Program Manager/Project Officer shall review and evaluate the use of these Plans. Upon completion of the monitoring activities, the Program Manager/Project Officer shall assess the data quality of the planned activity.

### 5.4 Quality Management Plans for External Organizations

The following requirements must be met by those organizations submitting QMPs to Region 4 for grants, contracts, and cooperative agreements:

- 5.4.1 The QMP must satisfactorily address the main topic areas covered in “EPA Requirements for Quality Management Plans,” EPA QA/R-2, EPA240/B-01/002, March 2001, or most recent version.
- 5.4.2 QMPs must include a description of review and approval process for specific QAPPs covered by the assistance agreement. QMPs will be reviewed by the RQAM and the appropriate assistance agreement project officer. The appropriate assistance agreement project officer will coordinate the review of the QMP for their specific extramural agreement. QMPs shall be approved for a period of no longer than five years.
- 5.4.3 The Grants Management Office within the Office of Policy and Management will review extramural agreements before award to assure that all Agency quality requirements have been documented. The RQAM will provide GMO staff and regional project officers with a listing of approved QMPs and their expiration dates for State and Tribal continuing assistance agreements.

### 5.5 Quality Assurance Project Plans for External Organizations

The following requirements must be met by those organizations submitting QAPPs to Region 4 for grants, cooperative and interagency agreements:

- 5.5.1 The QAPP must satisfactorily address the main topic areas covered in The



document entitled “EPA Requirements for Quality Assurance Project Plans”, EPA QA/R-5, Final, March 2001.

5.5.2 In reviewing QAPPs, the RQAM or his/her designee will use the graded approach, recognizing that each data collection project is different. Simpler projects may require QAPPs which are not as detailed as those of more complex projects.

5.5.3 The document entitled “EPA Guidance for Quality Assurance Project Plans” EPA QA/G-5, Final, December 2002, provides a detailed look at the process of developing a QAPP.

## **6.0 REGIONAL QUALITY SYSTEM for INTERNAL DATA**

As noted earlier, QA data generation activities fall into two broad categories: internal and external. This section describes the quality system requirements for environmental data generated by Region 4 organizations (internal data). The overall quality system policies, procedures, roles, and responsibilities are described in this QMP. At the project level, the region relies on a project level quality document to describe project quality assurance and quality control procedures: the quality assurance project plan. It is generally recognized within the region that other technical project level work plans, however named, must be equivalent to the QAPP. For example in the Superfund program, due to existing contract language and program precedents, a sampling and analysis plan coupled with a QAPP may be used to document project level technical activities.

### **6.1 Internal Data Operations**

EPA Project Managers or their designees are responsible for preparing QAPPs when the projects involve the collection of environmental data or the use of environmental technology. The RQAM is available to assist in the development of QAPPs by discussing the Agency’s requirements for QAPPs, but will not directly participate in writing the plan. The RQAM or his/her designee shall review and approve all QAPPs for internal data prior to data collection unless such projects are of a routine nature (for example, NPDES Compliance Sampling Inspections) with sampling and data quality requirements established in the organization’s Standard Operating Procedures (SOPs) and/or EPA regulations.

### **6.2 Designated Approving Officials**

A designated approving official (DAO) is a regional manager or staff person outside of the Office of Quality Assurance and Data Integration who has been delegated the authority to approve quality assurance project plans by the RQAM. In order to be authorized as a

DAO, the individual must meet the following requirements:

- 6.2.1 Satisfactorily complete an 8 hour training course provided by the RQAM on QAPP requirements and review. Completion of this training shall be documented by the RQAM with a certificate naming the individual as a DAO and shall be tracked by the division in which the DAO is employed.
- 6.2.2 Possess the necessary expertise in project management to review the QAPP.
- 6.2.3 Have no direct conflict of interest. A project manager who writes a QAPP for a project under his/her direction cannot approve that QAPP.
- 6.2.4 Document the QAPP review using a Region 4 Office of Quality Assurance and Data Integration (or equivalent) checklist. Refer to Appendix C for the checklist.

### 6.3 QA Operations for Contracts

Since the mission of the regional programs is to protect human health and the environment rather than to produce a manufactured product, it is not anticipated that most regional divisions will procure manufactured items which impact the quality of data. Therefore the inspection of routine procured items is not an element of the quality system for organizations other than SEDS. Because one of SEDS's primary missions is to produce data which support other divisional programs, SEDS's Branch QA Manuals and SOPs contain instructions on evaluating the suitability of manufactured items which are critical to data generation process (e.g. sampling equipment, laboratory instrumentation, reagents and supplies). The first line supervisors in SEDS are responsible for including quality specifications in purchase requests and for inspecting or delegating the inspection of equipment and consumables to assure the items meet the quality specifications.

Many regional divisions use contractors for the collection of environmental data or use of environmental technology. During the contract pre-award phase, the originating program division shall notify the RQAM of all contracts involving environmental data collection. Normally the types of contracts which will require the generation of quality assurance documentation are those in which services are procured. Examples of these types of service contracts include contractor analytical operations, sampling/field measurements, data assessment, site investigations, etc. The QA requirements in the Federal Acquisition Regulations (FAR) 46.202-4 and FAR 52.246-11 (*Higher-Level Contract Quality Requirement*, Feb 1999) apply to regional contracts involving the collection and use of environmental data. The appropriate project and contracting officer (PO and CO) are responsible for ensuring that all solicitations for work involving environmentally-related measurements meet the *Higher Level Quality Requirements* specified in FAR 52.246-11. In addition, the PO (a.k.a. contracting officer's representative) shall ensure that a QA Review Form has been completed in accordance with EPA Order 1900, the Contracts Management Manual. The PO is also responsible for including the RQAM as a technical

evaluation panel member on those contracts with a value of \$500,000 or greater, if the contracts involve environmental measurements or technology.

It is the responsibility of the Procurement Section within the Office of Policy and Management to assure that QA Review Forms, with appropriate signatures, are included in every solicitation package. The QA Review Form will specify if environmentally-related measurements are required under the contract's scope of work, and if so, which type of quality documentation is required under the contract. The default submissions for contracts requiring environmental measurements are a Quality Management Plan before award and a Quality Assurance Project Plan for each applicable project after award. The Quality Management Plan (QMPs) and Quality Assurance Project Plan may be combined into a single quality assurance document if agreed to before contract award by the contract PO and the RQAM. Prior to contract award, the Procurement Section will ensure that QMPs are reviewed and approved by the RQAM for those contracts requiring environmental measurements or technology.

## **7.0 REGIONAL QUALITY SYSTEM COMPONENTS**

Planning, implementation and assessment processes are necessary to effectively conduct environmental data collection operations and the use of environmental technology. The elements of the regional quality system include activities in the planning, implementation and assessment phases. The planning process is documented in QAPPs, the implementation phase is performed and overseen by the data user and/or project manager/leader, and the assessment phase is conducted as specified in the applicable project planning document. The components and procedures described below are used for the collection of environmental data by Region 4 personnel:

### **7.1 Data Quality Objectives**

The data quality objectives (DQOs) process is a systematic planning process which is used to delineate project-level elements. During the DQO process, the elements which are developed include project management, data generation and acquisition, project assessment and oversight, and data validation/usability. Detailed guidance for developing DQOs is provided in "Guidance for the DQO Process", EPA QA/G-4, Final, August 2000; and "Guidance for Data Quality Assessment - Practical Methods for Data Analysis," EPA QA/G-9, Final, July 2000. The Agency's DQO process is the preferred method of developing objectives for those projects requiring the collection of environmental data or the use of environmental technology. However, any systematic planning process may be used as long as it leads to the generation of a QAPP which meets EPA's requirements.

Having identified the need for an environmental data collection effort, the decision maker

(i.e., Branch Chief, Section Chief, Project Manager, etc.) is responsible for initiating the DQO development process. During the early planning phase of the investigation, the data user must clearly establish the intended use of the data, time and resource constraints, and in general terms, the quality of data needed. The project manager is responsible for development of DQOs that will facilitate the generation of sufficient data of the quality needed by the ultimate data user/decision maker. The DQO process requires interaction between the project manager, field and laboratory technical staff, QA staff, and secondary data users as appropriate. The DQOs developed will be used for the detailed design of the investigation and preparation of the QAPP.

The RQAM will be the focal point for providing guidance and review of DQO development. The RQAM will consult with other Regional technical staff on DQO issues outside the technical expertise available within the Office of Quality Assurance. A rigorous treatment of the statistical hypotheses and decision error portion of DQOs may require consultation with a statistician.

*Note: Many data collection activities mandated by EPA already have project objectives and data quality indicators (such as precision, accuracy and comparability) specified in the applicable regulations or in the methodology required by the regulations. In these instances it may not be necessary to proceed through all phases of formal DQO development. Regional staff having questions related to the development of DQOs should consult with the Regional Quality Assurance Manager.*

## 7.2 Quality Assurance Project Plan Contents

Region 4 relies on QAPPs coupled with detailed SOP's to define specific project QA/QC requirements. In preparing a QAPP, the project manager must identify the project objectives, sampling design, critical measurements to be performed, and discuss the QC activities to be conducted during the sampling, analytical, and validation phases of the project. The document entitled "EPA Requirements for Quality Assurance Project Plans," EPA QA/R-5, Final, March 2001, provides basic instructions for preparing QAPPs. The content of Regional QAPPs shall adhere to the requirements of EPA QA/R-5, most recent version. The document entitled "EPA Guidance for Quality Assurance Project Plans" EPA QA/G-5, Final, December 2002, provides a detailed look at the process of developing a QAPP. Within the region, different organizations may refer to the project-level planning document using terms such as "sampling and analysis plan" or "study plan." However named, the project-level planning document will contain the necessary elements specified in EPA QA/R-5, while at the same time considering the application of the graded approach to the planning document.

All regional projects requiring collection of environmental data or the use of environmental technology must have an approved QAPP prior to data collection. An exception to this requirement are those projects where immediate danger to human health

or the environment is present or suspected. Projects involving environmental technology shall follow the EPA "Guidance on Quality Assurance for Environmental Technology," (EPA QA/G-11), when this guidance is issued as a final document. The RQAM, or a designated approving official, shall review all QAPPs, provide input, recommend changes, and approve final plans. The RQAM may solicit assistance from regional technical staff when specialized expertise is needed to review certain QAPPs. Project QA activities are tracked by the appropriate Project Manager.

### 7.3 Standard Operating Procedures

Standard Operating Procedures (SOP's) are documented protocols for performing certain routine repetitive tasks. These tasks frequently involve such operations as sample collection, chain of custody, analysis methods, instrument or method calibrations, preventive and corrective maintenance, quality control, and data reduction.

#### 7.3.1 Preparation of SOPs

SOPs are prepared by the regional organization which has determined that a certain task, procedure, or job function must be performed in a uniform, consistent manner by multiple personnel. The purpose of an SOP is to assure that random error produced as a result of differences in performance of the task are minimized. It is advisable that SOPs be prepared by staff who are most knowledgeable in a specific task or procedure. The SOPs are reviewed by appropriate staff in the user organization, and at times by technical specialists in other organizations. The SOPs are prepared in document control format by the user and are to be maintained on permanent file by the originating organization. The EPA document entitled "Guidance for the Preparation of Standard Operating Procedures" (EPA QA/G-6), Final, March 2001, should be consulted for an example of the document control format. The second level supervisor (Branch Chief or equivalent) approves the SOP for use. SOPs are dynamic documents that are revised as needed. SOP revisions may be the result of changes in regulations, procedures, instruments and equipment, or by inadequacies noted during implementation and/or audits. Revisions are reviewed and approved as described above.

#### 7.3.2 Standard Operating Procedure Criteria

The following are considerations involved in the development and utilization of Standard Operating Procedures. SOPs should be:

- 7.3.2.1 Adequate to establish traceability of standards, instrumentation, samples, and environmental data.

- 7.3.2.2 Simple, so a user with basic education, experience and/or training can properly use them.
- 7.3.2.3 Complete enough so the user/reader follows the directions in a systematic manner through the sampling, analysis, and data-handling process.
- 7.3.2.4 Consistent with sound scientific/engineering principles.
- 7.3.2.5 Consistent with current EPA regulations and guidelines.
- 7.3.2.6 Consistent with the instrument manufacturers' specific instruction manuals.

#### 7.3.2 Activities Requiring Standard Operating Procedures

The following protocols related to the collection of environmental data will be addressed in SOPs:

- 7.3.2.1 General sampling procedures.
- 7.3.2.2 Analytical methodology.
- 7.3.2.3 Sample collection devices, storage containers, and sample additives such as preservatives.
- 7.3.2.4 Instrumentation selection and use.
- 7.3.2.5 Instrumentation calibration and standardization.
- 7.3.2.6 Instrument preventative and remedial maintenance.
- 7.3.2.7 Duplicate, spiked, blank samples and analysis.
- 7.3.2.8 Field and laboratory quality control procedures.
- 7.3.2.9 Sample documentation, sample custody, transportation, and handling procedures.
- 7.3.2.10 Field and laboratory safety.

7.3.2.11 Data management and assessment procedures.

7.3.2.12 Document control.

#### 7.4 Data Processing, Verification, and Validation

Data processing includes collection, reduction, transfer, verification, and storage. Precautions shall be taken each time the data are reduced, recorded, calculated, and transcribed to prevent the introduction of errors and the loss of information. Data processing requirements:

7.4.1 Collection: Each field and laboratory SOP, as appropriate, shall address the steps which must be used to avoid errors in the sample collection or sub-sampling process.

7.4.2 Verification: Data verification is the process of evaluating the completeness, correctness, and conformance/compliance of a specific data set against the method, procedural, or contractual requirements. Data verification procedures will be specified in the applicable laboratory SOP, QA Manual, QAPP, or data review SOP.

7.4.3 Validation: Data validation is defined as an analyte and sample specific process that extends the evaluation of data beyond method, procedural, or contractual compliance (i.e., data verification) to determine the analytical quality of a specific data set. Criteria for data validation shall be specified in the applicable QAPP.

7.4.4 Storage: Each SOP, as appropriate, shall indicate how specific types of data will be stored.

7.4.5 Transfers: Each SOP, as appropriate, shall describe procedures which shall be used to ensure that data transfer is error-free, and that no information is lost in the transfer. Data transfer steps shall be kept to a minimum.

7.4.6 Reduction: Each SOP, as appropriate, shall contain procedures for ensuring the correctness of data reduction processes. Data reduction includes all processes which change either the form of expression or quantity of data items. It is distinct from data transfer in that it entails a reduction in size (or dimensionality) of the data set. Each SOP, as appropriate, shall describe procedures for verifying the accuracy of the data reduction process.

## 7.5 Data Quality Assessment

Each QAPP should include procedures for assessing the quality of all environmental data generated for accuracy, precision, completeness, comparability and representativeness. Detailed guidance for assessment may be found in Guidance for Data Quality Assessment, EPA QA/G-9, January 1998.

## 7.6 Corrective Action

Each QAPP shall include provisions for QA reporting or feedback to the responsible management to ensure that early and effective corrective action can be taken when data quality falls outside established data quality objectives (acceptance criteria). Each QAPP shall also include provisions to keep management informed when corrective actions are necessary. Corrective action shall relate to the overall QA management scheme: who is responsible for taking corrective actions, when are corrective actions to be taken, and who follows-up to see that corrective actions have been taken and that they have produced the desired results.

## 7.7 Information Management

EPA's Office of Environmental Information (OEI) and the National Technology Services Division (NTSD) are responsible for managing the hardware, software and communications components which form the foundation of the Agency's information technology. NTSD has established the hardware and software standards with which the Region must conform. Region 4 managers and staff will observe all hardware and software standards as detailed in the NTSD Directives System at <http://basin.rtpnc.epa.gov/ntsd/directives.nsf>. This directive system is applicable to the personal computer (PC) platform, local area network and server platforms, open systems platforms, Agency electronic mail service, IBM Compatible Mainframe Platform, and Supercomputer Platform.

Region 4 will procure Agency-approved hardware and software that conforms with Agency-wide information management structure. Region 4's Information Management Branch (IMB) will assess significant changes in the Agency's hardware and software policy to determine the effect on the Region. In the event changes are required, IMB managers will work with regional managers to plan and implement appropriate modifications.

In the event that a Regional organization has a need to purchase or develop application software which is not on Agency contract, the software will be evaluated prior to purchase or during development. Software evaluation should be performed against written



performance/capability standards developed by the PC site coordinators and/or system administrators. Vendors must comply with the Agency standards provided by NTSD. Regional PC site coordinators and/or system administrators are responsible for evaluating software to determine its performance capabilities and documentation requirements.

## **8.0 QUALITY SYSTEM ASSESSMENT**

### **8.1 Assessment Management**

An effective QA System requires periodic assessment to determine if the system is operating as designed and to establish a basis for corrective action. At the organizational level, each affected organization will be assessed against the appropriate QMP. The RQAM or designee shall review and evaluate the implementation of selected QMPs, including the Region 4 QMP. At the project level, all data collection activities will be assessed against an approved QAPP. The RQAM or designee shall review and evaluate the implementation of selected QAPPs during the operational phase of the monitoring activity. Selection of projects will depend on the following criteria: projects supporting litigation, high visibility projects, and requests from Project Managers. Upon completion of the project activity, the Project Manager shall assess the actual performance of the planned activities and subsequent results. The final project report shall contain the results of this assessment and state whether the data collected meet the objectives of the project.

The QAPP shall ensure that:

- 8.1.1 The level of data quality required will be determined and stated in terms of precision, accuracy, completeness, comparability and representativeness, before the data collection effort begins.
- 8.1.2 All environmental data generated and processed will be of the quality and integrity established by each QAPP or by applicable EPA regulations as appropriate.

### **8.2 Types of Assessment**

Oversight of the data generation activities in Region 4 will be tailored to the nature of the activity and the associated management and administrative system. Assessments are the principal means in Region 4's QA Program to determine compliance with established QA Management and Project Plans. Different types of assessments are used to verify that management and measurement systems are operating properly, to assess whether data quality is adequately documented, and to evaluate the management of QA programs. Detailed guidance for assessment may be found in Guidance for Data Quality Assessment, EPA QA/G-9, Final, July 2000. The RQAM has the primary responsibility for conducting

audits at the management and project levels.

Four specific kinds of assessments will be used at appropriate times by the Region 4 RQAM to determine the status of measurement systems, the adequacy of the data collection systems, the completeness of documentation of data collection activities, and the abilities of program management to meet mandated data collection and data quality objectives. These four audit types are respectively, performance audits, technical system audits, data quality system audits, and management system reviews. Each type of audit is described below:

- 8.2.1 Performance audits are quantitative audits of the ability of an analytical system to obtain reliable data. These audits involve submission of proficiency test (PT) samples as unknowns to laboratories or other analytical systems. For the most part, these are part of national program audits such as the Water Supply PT Studies, Water Pollution PT Studies, DMR QA Studies, Air Intercomparison Studies, etc. These audits are used as one indicator of the data produced by NPDES Permittees, certified drinking water laboratories, and Superfund contract laboratories CLP). The Region 4 SESD laboratory routinely participates in these audits as appropriate. The region routinely sends performance audit samples with each set of samples submitted to the CLP. Special performance audit samples are requested by a regional project manager to audit a laboratory producing data for a potentially responsible party remedial investigation of a Superfund site.
- 8.2.2 Technical system audits are on-site environmental assessment activities. The audits are qualitative assessments of personnel, equipment, facilities, procedures, and QA activities. These audits are conducted at least biennially at state agencies and cover ambient air, water quality/water quality enforcement, drinking water, and hazardous wastes monitoring activities. Audits (known as Performance Audit Inspections (PAIs)) of NPDES permittees are conducted routinely in delegated states. PAI candidates are chosen by EPA and the states; performance in the DMR QA Studies is one of the criteria used. Other audits are conducted at RCRA facilities and CERCLA investigations at the request of the program division. The Region 4 SESD chemistry and microbiology laboratory activities are audited every three years by EMSL-Cincinnati. Audits of randomly selected regional activities are conducted as resources permit, or a particular activity is audited if there is evidence of inadequate performance.
- 8.2.3 Data quality audits are quantitative audits in which data are reviewed and evaluated following collection to determine the quality and usability of the data. These audits are conducted by Office of Quality Assurance staff on all contract laboratory program (CLP) data for CERCLA and any programmatic analytical data which is

contracted through SESD. Data quality audits are performed on data from other sources as requested by the appropriate project manager or leader.

- 8.2.4 A management system review (MSR) is an assessment of an organization's ability to implement and manage an effective QA program. An MSR of the regional quality system will be conducted annually. This MSR may consist of a review of all organizations within the region, or if resources do not permit, of a selected organization within the region, for example, the Air, Pesticides and Toxics Management Division. MSRs may also be conducted of any regional contractor, or extramural organization which receives funding from the region. These audits are not routinely scheduled but will be conducted when results of other types of audits indicate problems with the organization's quality system.

### 8.3 Corrective Actions

Results of these various types of audits listed in Section 8.2 are reported to the appropriate Division Director, Branch Chief, Project Officer, etc. The RQAM will submit written findings and corrective actions, along with a specific time frame for responding to the findings. Assessment corrective actions will be tracked by the RQAM or his/her designee. A written response with a satisfactory corrective action from the affected organization or project shall be considered as an appropriate response.

## 9.0 **DOCUMENTS and RECORDS**

The Federal Records Act of 1950, as amended (44 U.S. C. 3101), requires that all Federal agencies make and preserve records containing adequate and proper documentation of their organization, its functions, policies, decisions, procedures, and essential transactions. These records are public property and must be managed according to applicable laws and regulations. In a Federal Agency, files and records serve as the official memory of the agency's activities. Records of the agency come in many forms, formats and storage media. Because of legal statutes and regulations, all Federal agencies are required to create, maintain, and retain their files, records and information as a valuable resource. All Federal records are subject to Federal requirements regarding their creation, maintenance and retention. These standards, set by the National Archives and Records Administration (NARA), include guidelines on the information's ownership, value, and availability.

### 9.1 Region 4 Records Management System

Region 4 has issued standard operating procedures for managing records within the region. Details of these procedures are described in documentation prepared by each Division and are based on identifying the EPA Records Schedule applicable to a particular document.

The standard operating procedures are based on the requirements of EPA Information Resources Management Manual (Directive 2100) and the EPA Records Management Manual (Directive 2160), July 1984. Quality-related records are not managed separately, but are included in the appropriate EPA Records Retention Schedule based on Directives 2100 and 2160. The following general procedures for records management are in place in Region 4.

- 9.1.1 Each organizational element (Division or Office) is assigned record keeping responsibility in accordance with its functional responsibilities and duties. Records and information created, received, maintained, or acted upon shall be maintained in accordance with EPA and NARA approved Records Retention Schedules.
- 9.1.2 Managers and supervisors will be held responsible for ensuring that EPA employees, and contractor staff (working inside or outside EPA) are adhering to Regional, EPA, and NARA record keeping procedures.
- 9.1.3 Mandatory Records Management training sessions will be provided for all EPA employees, managers, and contractor staff on record keeping procedures and FOIA requirements. Such training classes shall be provided and attendance required once every three years or as changes in requirements warrant.
- 9.1.4 Files and agency records may not be checked out to EPA or contractor staff unless the required records management training courses have been completed.
- 9.1.5 Files and records may not be checked out for more than 90 days. File check-out procedures shall be followed by all records personnel. A monthly report shall be provided to the program management and Regional Records Management of all records and files removed for more than 90 days. A response will be required from the program manager for overdue records and files.
- 9.1.6 A flag in the records circulation system will indicate site files that have been checked out and not returned for 6 months or more. This includes files sent to outside contractor staff. The user will be notified for the files to be returned to the records center. Manager approval will be needed for site files to be checked out longer than 6 months.
- 9.1.7 A chain of custody form and receipt is required when files are checked out from the records centers, delivered to an employee, contractor staff, and returned to the record centers. User responsibility for checked out files is established by this procedure and the user is responsible to ensure that the returned files and records are complete, in proper sequence or order, condition, and is returned in the same

condition in which they were received.

- 9.1.8 EPA employees leaving the agency must return all records to the records center including any records in their workstation that have never been placed in the record center. Supervisors and managers shall be responsible to ensure that files and records are returned.
- 9.1.9 Files, records and information shall be created, maintained, and retained in accordance with EPA and the Regions CBI, Privacy, and Vital Record Protection program requirements.
- 9.1.10 To improve FOIA records reviews and request, the Region shall implement a records system which designates a document as the original or a copy, which provides for a release determination to be made at the time of record creation, and which negates the need for files to be repeatedly reviewed each time a FOIA request comes in.
- 9.1.11 Electronic records and information held in electronic form and format shall be maintained in accordance with approved and issued EPA and NARA guidelines and retained in accordance with approved Records Retention Control Schedules.
- 9.1.12 Files, records and information shall not be destroyed except in accordance with EPA and NARA guidelines, requirements and Records Retention Control Schedules. All records destroyed will have a Certificate of Destruction verifying their destruction in accordance with such guidelines and requirements.

## **10.0 QA COMMUNICATION/REPORTING/WORK PLAN**

The purpose of communication is to ensure that staff in different programs can effectively develop and implement programs, perform activities, and resolve problems related to the generation of environmental data and the use of environmental technology. In order to effectively implement the regional quality system, communications must occur between the RQAM and regional managers and staff. The Office of Environmental Information's Quality Staff (OEI/QS) is the focal point for policy and guidance on the Agency's quality system. The RQAM or designee participates in monthly conference calls with the OEI/QS and other regional QAMs in order to be aware of new or revised QA policies as well as implementation issues associated with the Agency-wide quality system. Regional requests for assistance, interpretation, and action will be forwarded by the RQAM to the appropriate OEI/QS member. The RQAM will exchange QA information with the Regional QA Workgroup, Regional Program Managers, Regional Staff, EPA Laboratories, Headquarters Program Offices, and other Regions as needed to accomplish the

implementation of the regional quality system.

## 10.1 Regional Communication

The RQAM shall exchange information with Regional Programs Managers, Project Officers, QAWG, Technical Staff, and State/Tribal QA Officers.

10.1.1 A primary means of communication among Regional staff is the QA Work Group. The duties and responsibilities of the Work Group are described in section 4.2.5 of this document.

10.1.2 A primary method of RQAM communication with the State/Tribal QA community is annual meetings of State/Tribal Laboratory and QA personnel sponsored by SESD. The State/Tribal QA Officers communicate with appropriate environmental monitoring personnel, the local Agency QA Officers, and industrial QA Officers.

## 10.2 Annual Report and Work Plan

By November 1 of each year, the RQAM shall submit a QA Annual Report and Work plan to Regional Management and to the Director of OEI/QS. This report shall reflect the implementation status of the Region 4 QA Program. The Work Plan will describe all planned QA activities for the fiscal year beginning in October.

The QA Report shall contain as a minimum the following types of information:

10.2.1 Implementation Status of Regional QA Program.

10.2.2 Revisions to Regional Quality Management Plan.

10.2.3 Significant QA-related needs i.e., new policies, changes to existing policies, guidance documents, audit protocols, etc.

10.2.4 Data Quality Objectives.

10.2.5 Status of QA Program/Projects and Standard Operating Procedures.

10.2.6 Assessments conducted

10.2.7 QA Program resources

#### 10.2.8 QA training received and provided

### 10.3 QA Work Plan

The QA Workplan shall contain as a minimum the following types of information:

10.3.1 Total proposed EPA full time employees (FTE) for supporting QA management activities in Region 4.

10.3.2 Total proposed EPA FTEs for QA/QC support activities.

10.3.3 Total dollar amounts proposed for QA travel for oversight and audits.

10.3.4 Total dollar amounts proposed for QA training.

10.3.5 Brief description of major QA/QC activities.

### 10.4 National Meetings

In addition to the regular communication/reporting activities described above, the RQAM, or designee, will participate, at a minimum, in EPA's Annual QA Conference. The RQAM, or designee, will participate in other meetings and workgroups, which help to advance national and regional QA goals and to assist with the implementation of the regional quality system.

### 10.5 Resources

National Program Managers (NPMs) set staffing levels for activities in each of the programs and regions. At present, no FTEs are specifically designated by the NPMs for the implementation of the mandatory Agency-wide quality system. In Region 4, distribution of QA-related resources, including FTEs, are determined by the Regional Administrator and Division Directors. These senior managers must balance quality system resource needs with other program resource needs. The SESD Director, with input from the RQAM, will recommend staffing and resource needs for maintaining the regional quality system.

## 11.0 **PEER REVIEW**

Two Peer Review protocols exist within the Region. The first, Region 4 Order 2200.1,

entitled Review and Clearance of Materials for Public Distribution was issued April 15, 1982. The second protocol, entitled Region 4 Standard Operating Procedures for Peer Review, October 1, 1995 - September 30, 1996, was established in response to the EPA Administrator's June 7, 1994 Peer Review Policy Statement.

#### 11.1 Internal Peer Review

Regional Order 2200.1 establishes a protocol for peer review of technical reports, study plans, and documents intended for public release. The purpose of this protocol is to ensure that such materials are based on sound scientific, technical, legal, and policy principals. Division and Office Directors are responsible for initiation of review and clearance of applicable documents generated within their respective areas. This peer review process is an internal Region 4 review conducted by a Peer Review Panel composed of the following members:

Deputy Regional Administrator, Chairman  
Director, Science and Ecosystem Support Division  
Assistant Regional Administrator for Policy & Management  
Director, Office of Regional Counsel  
Director, Office of Congressional and External Affairs  
Director, Air, Pesticides and Toxics Management Division  
Director, Waste Management Division  
Director, Water Management Division  
Regional Quality Assurance Manager

#### 11.2 External Peer Review

Region 4 Standard Operating Procedures for Peer Review, October 1, 1995 - September 30, 1996, provides for an objective, critical review of a specific Agency major scientific and/or technical work product by independent peer reviewer(s). An independent peer reviewer is an expert not associated with the generation of the specific work product, either directly by the substantial contribution to its development, or indirectly by consultation during the development of the specific product. The purpose of an independent peer review is to disclose any technical problems or unresolved issues in a preliminary work product in order to revise the work product. The peer review process will allow the final work product to reflect sound scientific and/or technical information. Each Division/Office Director has the responsibility for selecting major work products subject to independent peer review. A Regional Peer Coordinator responsible for leading the peer review activities is appointed each year by the Regional Administrator. Specific roles and responsibilities are detailed in the Peer Review SOP.



## **12.0 TRAINING**

Each manager will ensure that all personnel performing duties which require the use of environmental data or technology will have the needed education, experience, and training. Formal education and experience are prerequisites of each federal job series. Personnel who may require QA training include, but are not limited to, laboratory technicians, analysts, supervisors, project officers, project managers, field project leaders, and regional QA staff. QA training needs will be identified by supervisors during annual performance evaluations and through career development plans. Supervisors should contact the RQAM to determine if the identified training needs can be met through regional training provided by the RQAM/staff, or if other sources are needed for the training. The RQAM will assist the supervisor in locating the most appropriate QA training to meet the need which has been identified.

The training needs of the RQAM and QA staff are not static, but change as the various environmental programs mature. Therefore, training needs of the RQAM and staff will be addressed in the Region's Annual QA Report/Work Plan. The Report/Work plan shall be submitted annually to the OEI/QS Director for review.

At least annually, the RQAM, with assistance from the Office of Quality Assurance and Data Integration and other SESD organizations, will present one of the following training courses:

- ▶ "Introduction to the Data Quality Objectives Process",
- ▶ "Development and Review of QAPPs",
- ▶ "Environmental Data Generation and Evaluation".

If there is sufficient demand for more than one QA training per year, OQA will provide multiple training courses. The RQAM is available to discuss specific training needs with supervisors or staff. Courses may be developed by the RQAM and staff to meet specialized training needs. In fact, the course entitled "Environmental Data Generation and Evaluation" was developed specifically in response to requests from regional and state RCRA staff for training to determine how environmental data are produced and what quality indicators should be considered by data users. Also, the RQAM or an OQA staff member, will provide a one hour presentation on QA for Financial Assistance Agreements to each Grants Project Officer training course which outlines the minimum set of documentation needed to meet the Agency's QA requirements for grants and cooperative agreements. The Grants PO training is required of all new personnel assuming PO responsibility for financial assistance agreements and is normally presented annually.

The RQAM must balance the resources needed to perform programmatic quality assurance support functions (data verification, performance audits, technical systems audits, QAPP review, etc.) with the resources needed to perform QA training. Due to limited resources

for QA training, the Region's plan of action will be to present training to Region 4 EPA and contractor personnel prior to providing training to the States and Tribes. As more regional and contractor personnel receive QA training, the courses will be opened to State and Tribal personnel who desire this type of training. Due to the lack of dedicated training resources, the region at this time does not provide QA training to private sector personnel.

### **13.0 IMPLEMENTATION REQUIREMENTS AND SCHEDULE**

Implementation of the Agency's Mandatory QA Program requires that each major milestone be identified and scheduled for accomplishment. Major National/Regional milestones shall be identified, scheduled, and progress reported in the Region 4 Annual QA Report/Work Plan.

## Appendix A

### REGION 4 ORGANIZATIONAL CHARTS

See: <http://www.epa.gov/region4/divisions/>

Appendix B

REGION 4

MAJOR PROGRAM ELEMENTS

**Appendix B      MAJOR PROGRAM ELEMENTS**

<b>ACTIVITY</b>	<b>APPLICABLE LAW</b>	<b>RESPONSIBLE DIVISION</b>	<b>SESD BRANCH PROVIDING SUPPORT</b>
<b>Ambient Air Monitoring for Criteria Pollutants</b> -- Delegated to the states. The Region has an overview/ technical assistance role. Special studies (i.e., Air Toxics) are conducted to support state programs.	CAA	APTMD	EIB, ASB
<b>Stationary Source Enforcement</b> -- Delegated to the states. The Region has an overview/technical assistance role.	CAA	APTMD	EIB, ASB
<b>Mobile Source Inspections and Maintenance</b> -- Delegated to the states. The Region has an overview/ technical assistance role.	CAA	APTMD	EIB, ASB
<b>Pesticide Use/Misuses</b> -- Delegated to the states. The Region has an overview/ technical assistance role. The states regulate and monitor the manufacture, sale, and use of pesticides.	FIFRA	APTMD	EIB, ASB, OQA
<b>PCB and Dioxin Inspections</b> -- Inspections are conducted at transformer stations, substations, etc. Program inspectors conduct sampling; analyses are conducted by SESD and contract laboratories.	TSCA	APTMD	EIB, ASB
<b>Asbestos Inspections</b> -- Overview of asbestos removal from schools and overview of renovation and demolition of buildings. Sampling and analyses are conducted by contractors.	TSCA	APTMD	OQA

<b>ACTIVITY</b>	<b>APPLICABLE LAW</b>	<b>RESPONSIBLE DIVISION</b>	<b>SESD BRANCH PROVIDING SUPPORT</b>
<b>Water Quality Monitoring</b> -- Most programs delegated to the states. Activities involve both fixed station networks and intensive studies. The Region has an overview/technical assistance role which includes special studies to support state programs.	CWA	WMD	EIB, EAB, ASB, OQA
<b>Water Quality Enforcement</b> -- Delegated to all states. Several types of compliance inspections are conducted as overview for delegated states.	CWA	WMD	EIB, EAB, ASB, OQA
<b>Dredge and Fill</b> -- Investigations are conducted by SESD to support permitting decisions by the Region and for enforcement actions by the Department of Justice.	CWA	WMD	EIB, EAB, ASB, OQA
<b>RCRA Enforcement</b> -- The program is delegated to the states. Several types of inspections are conducted by SESD and contractors. These include inspections of generators, transporters, and disposal facilities.	RCRA	Waste Div.	EIB, ASB, OQA
<b>Investigations of Uncontrolled Hazardous Waste Site</b> -- Several types of investigations are conducted to support listing of sites on the NPL and for remedial actions (immediate removal or clean-up activities). Investigations are conducted by contractors, by states under cooperative agreements, by potentially responsible parties under consent orders and by SESD. The Region overviews all extramural investigations.	CERCLA	Waste Div.	EIB, EAB, ASB, OQA
<b>Monitoring of Public Water Supplies</b> -- Program is delegated to the states. The Region has an overview/technical assistance role. SESD conducts special studies in support of state programs.	SDWA	WMD	EIB, ASB, OQA
<b>Underground Injection Control</b> -- Program is delegated to the states. The Region has an overview/technical assistance role. SESD conducts special studies in support of the state programs.	SDWA	WMD	EIB, ASB

ACTIVITY	APPLICABLE LAW	RESPONSIBLE DIVISION	SESD BRANCH PROVIDING SUPPORT
<b>Investigations of Leaking Underground Storage Tanks</b> -- The RCRA program (UST) is delegated to the states. The Region has primary responsibility for the UST program in Georgia and overviews the other seven state programs.	RCRA	WMD, Waste Div.	EIB, ASB

**Appendix C**

**REGION 4**

**QUALITY ASSURANCE PLAN CHECKLIST**



**QAPP Title:**  
**Project Location:**  
**Originating Organization:**  
**QAPP Date:**  
**Receipt Date:**  
**Review Date:**  
**Reviewer:**  
**SESD Project # (for QAPP review):**

**USEPA**  
**REGION 4 OFFICE of QUALITY ASSURANCE and DATA INTEGRATION**  
**QAPP REVIEW CHECKLIST**

P = Present & Acceptable; NP = Not Present; I = Incomplete; NA = Not Applicable

ELEMENT	COMMENTS
A1. Title and Approval Sheet	
Title	
Organization's name	
Dated signature of project manager	
Dated signature of quality assurance officer	
Other signatures, as needed	
A2. Table of Contents	
A3. Distribution List	
A4. Project/Task Organization	
Identifies key individuals, with their responsibilities (data users, decision-makers, project QA manager, subcontractors, etc.)	
Organization chart shows lines of authority and reporting responsibilities	
A5. & Problem Definition/Quality Objectives A7	
Clearly states problem or why data is needed	
Provides historical and background information	
Identifies the decision(s) to be made as a result of the project or indicates how the data will be used	
Describes the type of data (e.g. screening or definitive) needed	
Defines geographic, spatial, and/or temporal boundaries	
Provides a decision rule or "if/then" statement <i>Note: Some projects, especially research or preliminary investigations, may not require a specific "if/then" statement.</i>	

ELEMENT	COMMENTS
States decision error limits, if applicable <i>Note: Projects which are based on authoritative rather than statistical sampling designs will not have quantitative decision error limits</i>	
A6. Project/Task Description	
Lists measurements to be made or information to be gathered	
Cites <u>applicable</u> technical or regulatory standards or criteria <i>Note: Not all projects are driven by regulatory standards, e.g., some grants</i>	
Describes special personnel or equipment requirements <i>Note: This statement applies only to unique situations and is normally not required for routine environmental projects.</i>	
Provides work schedule	
A8. Special Training Requirements/Certification Listed	
States how provided, documented, and assured	
A9. Documentation and Records	
Notes required project and QA records/reports	
Lists information and records to be included in data report (e.g., lab/field raw data, field logs, lab records, results of QC checks, problems encountered)	
Gives retention time and location for records and reports	
B1. Sampling Process Design (Experimental Design) States the following:	
Type and number of samples required	
Sampling design and rationale (either authoritative or statistical and why this sampling approach was chosen)	
Sampling locations and frequency	
Provides geographically referenced sampling locations <u>or</u> provides criteria for selecting sampling locations in the field.	
Sample matrices	
Classification of each measurement parameter as either critical or needed for information only	
Appropriate validation study information for nonstandard sampling situations (if applicable)	
B2. Sampling Methods Requirements	
Identifies sample collection procedures and methods	
Identifies individuals responsible for corrective action	
Describes or references process for preparation and decontamination of sampling equipment	
Describes or references selection and preparation of sample containers and sample volumes	

ELEMENT	COMMENTS
Describes or references preservation methods and maximum holding times	
B3. Sample Handling and Custody Requirements	
Describes or references sample handling requirements	
Describes or references chain-of-custody procedures, if required	
B4. Analytical Methods Requirements	
Identifies laboratory(ies) to conduct testing	
Identifies analytical methods to be followed (with all options)	
Provides validation information for non-standard analytical methods, if applicable	
Identifies individuals responsible for corrective action	
Specifies needed laboratory turnaround time	
B5. Quality Control Requirements	
Identifies or references type and frequency of QC procedures for <u>each</u> sampling, analysis, or measurement technique	
Identifies or references associated acceptance criteria for QC procedures	
Identifies or references corrective action when acceptance criteria are not met and documentation of corrective action	
Provides or references QC statistics used to determine precision and bias	
B6.& B7. Instrument/Equipment Testing, Instrument Calibration and Frequency	
Identifies or references inspection/acceptance of sampling and measurement equipment	
Describes or references equipment preventive and corrective maintenance	
Identifies equipment needing calibration and frequency for such calibration	
Notes required calibration standards and/or equipment	
Cites calibration records and manner traceable to equipment	
B8. Inspection/Acceptance Requirements for Supplies and Consumables	
States inspection and acceptance criteria for supplies and consumables	
Notes responsible individuals	
B9. Data Acquisition Requirements for Non-direct Measurements	
Identifies type of data needed from non-measurement sources (e.g., computer databases, literature and files), along with acceptance criteria for their use, if applicable	
Describes any limitations of secondary data	

ELEMENT	COMMENTS
Documents rationale for original collection of data and its relevance to this project	
B10. Data Management	
Describes or references data transformation, transmittal, and reduction procedures	
Describes or references data analysis procedures including summary statistics	
Describes data management procedures used to process, compile, and store data including necessary computer hardware and software, if applicable	
C1. Assessments and Response Actions	
Lists required number, frequency and type of assessments, with approximate dates and names of responsible personnel ( <b>assessments include but are not limited to peer reviews, management systems reviews, technical systems audits, performance evaluations, and data quality audits</b> ) <i>Note: Not all projects require every type of assessment. Type of assessments will depend on project length, complexity, and importance of decision to be made with the data.</i>	
Identifies individuals responsible for corrective actions	
C2. Reports to Management ( <i>Note: Written reports to management are more critical for long term projects with major human health or policy implications</i> ) Identifies frequency and distribution of reports, if applicable, for:	
Project status	
Results of performance evaluations and audits	
Results of periodic data quality assessments	
Any significant QA problems	
Preparers and recipients of reports	
D1. Data Review, Validation, and Verification & D.2 <i>Note: This process may be combined with the data quality audit, Element C1</i>	
States or references criteria for accepting, rejecting, or qualifying data (acceptance criteria may be based sample handling, shipping, and storage criteria as well as field and laboratory QC indicators for precision, bias, sensitivity and contamination)	
Includes project-specific calculations or algorithms	
Describes or references process for data validation and verification	
States the percentage of data to be reviewed	
Describes responsible organizations/individuals	
Identifies method for conveying these results to data users	
Identifies issue resolution procedure and responsible individuals	
D3. Reconciliation with User Requirements	

## REGION 4 QAPP REVIEW CHECKLIST (CONTINUED)

P = Present & Acceptable; NP = Not Present; I = Incomplete; NA = Not Applicable

ELEMENT	COMMENTS
Describes process for reconciling project results with DQOs and reporting limitations on use of data	

*Final QAPP disposition:*

\_\_\_ *Approved, no comments*

\_\_\_ *Approved with comments, resubmittal **not** required*

\_\_\_ *Conditionally approved, comments must be addressed, resubmittal required*

\_\_\_ *Not approved, comments must be addressed, resubmittal required*

### References

EPA Requirements for Quality Assurance Project Plans, EPA QA/R-5, EPA/240/B-01/003, March, 2001

EPA/600/R-98/018, Guidance for Quality Assurance Project Plans, EPA QA/G-5, EPA/600/R-98/018, February, 1998

(Available from EPA's Website: <http://www.epa.gov/quality>)